4748. (F. D. C. No. 34362. S. No. 878 L.)

INFORMATION FILED: 3–24–53, S. Dist. Fla., against Henry Gilman and Rudolph R. Scher, partners in the partnership of Park Pharmacy, Miami, Fla., and Meyer Colten, a pharmacist.

CHARGE: On 11–7–51, while held for sale, *Seconal Sodium capsules* were dispensed once without a prescription. Such act of dispensing resulted in the drug being misbranded as follows: 502 (b) (2)—the drug failed to bear a label containing an accurate statement of the quantity of contents; 502 (d)—the drug contained a chemical derivative of barbituric acid, and the label of the drug failed to bear the name and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; and 502 (f) (1)—the labeling of the drug failed to bear adequate directions for use.

DISPOSITION: The defendants filed a motion to dismiss the information, and on 4–17–53, the motion was denied. Thereafter, the defendants entered pleas of nolo contendere, and on 1–6–56, Gilman and Scher were each fined $100 and Colten $50.

4749. (F. D. C. No. 33764. S. Nos. 1–940 L, 1–954 L, 1–961 L.)

INFORMATION FILED: 4–29–53, S. Dist. Fla., against Warfield Thirty-Sixth St. Corp., t/a Warfield Drug Co., Miami, Fla., James J. Weinberger, president of the corporation, and Louis Finkelstein and Ralph Swisko, pharmacists.

CHARGE: Between 12–3–51 and 1–28–52, while held for sale, *pentobarbital sodium capsules* were dispensed 3 times without a prescription. Such dispensing resulted in the drug being misbranded as follows: 502 (b) (2)—the drug failed to bear a label containing an accurate statement of the quantity of contents; 502 (d)—the drug contained a chemical derivative of barbituric acid, and the label of the drug failed to bear the name and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; and 502 (f) (1)—the labeling of the drug failed to bear adequate directions for use.

DISPOSITION: The defendants filed a motion for dismissal of the information, and on 6–29–54, this motion was denied. The defendants then entered pleas of nolo contendere, and on 1–28–56, the court fined each defendant $100.

4750. Herb mix. (F. D. C. No. 37539. S. No. 16–094 M.)

QUANTITY: 4 340-lb. drums, 48 4-oz. bags, and 12 sample bags, each containing about 2 tablespoonsful, at Tacoma, Wash., in possession of Saunders' Health Service.

SHIPPED: 11–12–54, from New York, N. Y.

LABEL IN PART: (Bag) "Mixed Herbs No. One Contains: Yam, Culvers, Althea, Mandrake with Cascara."

ACCOMPANYING LABELING: A letter dated "July 23, 1954" and signed "Nina M. Moon" reading in part "Mixed Herbs #1 * * * saved me from an operation for gall-stones. Everyone who buys gets the same results as a liver cleanser." The letter was on display in front of the retail counter on the premises of Saunders' Health Service.

RESULTS OF INVESTIGATION: The article was shipped from New York, N. Y., in bulk drums and, after its receipt at Tacoma, Wash., by the consignee, a portion of the article was repacked into the bags described above.

LIBELED: 12–21–54, W. Dist. Wash.

CHARGE: 502 (a)—the labeling accompanying the article while held for sale contained false and misleading representations that the article was an adequate and effective treatment for gallstones and for cleansing the liver; and 502 (f) (2)—the article was essentially a laxative, and its labeling, while held for sale, failed to warn against use of the article when symptoms of appendicitis are present and failed also to warn that frequent or continued use of the article may result in dependence on laxatives.

DISPOSITION: 1–26–55. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

4751. Posterior pituitary injection. (F. D. C. No. 37287. S. No. 88–418 L.)

QUANTITY: 44 cartoned vials at Buffalo, N. Y., in possession of Direct Laboratories, Inc.

SHIPPED: 2–24–53, from Chicago, Ill.

LABEL IN PART: (Carton & vial) "No. 2261 10 cc. vial Posterior Pituitary Injection (Surgical) Double U. S. P. strength Each 1 cc. represents: Posterior Pituitary 20 USP units Chlorobutanol 5 mg. (8/100 gr.) * * * Water for injection USP q. s. 1 cc. * * * Administration: Intramuscular or Subcutaneous. * * * Direct Laboratories, Inc. Buffalo 4, New York."

RESULTS OF INVESTIGATION: The article was shipped in bulk, and after its receipt by the consignee, it was repackaged and relabeled. Examination showed that the article contained 73 percent of the declared posterior pituitary potency instead of 85 percent as required by the United States Pharmacopeia.

LIBELED: 10–4–54, W. Dist. N. Y.

CHARGE: 501 (b)—the strength of the article while held for sale differed from the standard for posterior pituitary injection set forth in the United States Pharmacopeia.

DISPOSITION: 11–4–54. Default—destruction.

4752. Chorionic gonadotropin. (F. D. C. No. 37649. S. No. 77–276 L.)

QUANTITY: 99 packages at Philadelphia, Pa.

SHIPPED: 8–16–54, from Los Angeles, Calif.

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than 50 percent of the declared amount of chorionic gonadotropin potency.

LIBELED: 2–9–55, E. Dist. Pa.

CHARGE: 501 (c)—the strength of the article while held for sale differed from that which it was represented to possess; and 502 (a)—the label statement "Chorionic Gonadotropin (Lyophilized) 5,000 I. U." was false and misleading.

DISPOSITION: 4–4–55. Default—destruction.

4753. Liver-folic acid B_{12}. (F. D. C. No. 37509. S. No. 89–577 L.)

QUANTITY: 63 vials at Minneapolis, Minn.

SHIPPED: 9–3–54, from Philadelphia, Pa.

RESULTS OF INVESTIGATION: Analysis showed the article contained approximately 70 percent of the declared amount of vitamin B_{12}.

LIBELED: 12–9–54, Dist. Minn.

*See also No. 4745.